K011465

JUN - 8 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Submitted By:

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2.0 Date Submitted

May 11, 2001

3.0 Device Name(s):

3.1 Proprietary Names

SYNCHRON CX® PRO Systems
(SYNCHRON CX4 PRO, SYNCHRON CX5 PRO, SYNCHRON CX7 PRO, SYNCHRON CX9 PRO)

3.2 Classification Names

Discrete photometric chemistry analyzer for clinical use [862.2160]

4.0 Legally Marketed Device

The SYNCHRON CX® PRO Systems (CX4 PRO, CX5 PRO, CX7 PRO and CX9 PRO models) claim substantial equivalence to the SYNCHRON CX® DELTA Systems (CX4 DELTA, CX5 DELTA, CX7 DELTA, CX9 ALX models) currently in commercial distribution. FDA 510(k) Number K950958.

5.0 Device Description

The SYNCHRON CX DELTA Systems are fully automated, computer controlled, random access clinical chemistry analyzers intended for the *in vitro* determination of specific analytes of clinical interest in biological fluids such as serum, plasma, urine, and cerebral spinal fluid (sample type is chemistry dependent). The analyzers operate in conjunction with reagents, calibrators, and controls designed for use with the system. The instruments feature bar code identification of samples and reagents. The instruments automatically deliver samples, reagents and reaction constituents to the appropriate reaction vessel (cuvette, flow cell, or cup). The CX4 DELTA system is a spectrophotometric module that analyzes up to 30 analytes per sample. The CX5 DELTA systems adds an additional electrolyte module to analyze

up to 35 analytes per sample. The CX7 DELTA and CX9 ALX systems combine a nine-chemistry STAT module (including electrolytes) with the spectrophotometric module to analyze up to 39 analytes per sample; the CX9 ALX and CX7 Delta models differ in name and appearance only. Major hardware components include a reagent compartment, sample and reagent cranes, cartridge chemistry section (CX4 DELTA, CX5 DELTA, CX7 DELTA, CX9 ALX), electrolyte module (CX5 DELTA), STAT module (CX7 DELTA, CX9 ALX), sample carousel and crane, hydropneumatics, electronics, and power supplies.

The CX PRO Systems employ Version 6.0 software to incorporate the use of the following additional features:

1. Obstruction Detection and Correction (ODC)
The ODC feature enables the system to detect and recover from complete obstruction of the sample probes due to clotted or viscous fluid. The feature is optional and may be enabled by the user in the system setup software. The system automatically initiates a clot removal process to prevent further obstruction in the system that includes probe flushing, verification of cleared probe status, and operator notification. The key hardware components include a pressure sensor, fittings, and cable and tubing assemblies.

2. On-board Sample Dilution (OBSD)
The OBSD feature implements on-board sample dilution for the select cartridge chemistries. The CX PRO system will automatically perform the appropriate sample dilution for select urine mode assays (1:10 dilution) and immunoprotein assays (1:26 dilution) using a system diluent cartridge. The final result is automatically multiplied by the appropriate dilution factor. There are no new hardware components to support this feature.

3. Serum Indices (SI)
The SI feature implements serum index methodologies for hemolysis, icterus, and lipemia. The optional, operator-enabled feature is intended for the assessment of serum and plasma sample integrity only, not for patient diagnosis. The CX PRO system performs the analyses for all three serum indices from a single cuvette using 14 ul of sample and system Diluent 1. Internal calculations are done in the system software; there are no new hardware components to support this feature.

4. Modem Connection (MC)
The MC feature allows remote upload to a Beckman Coulter site of the diagnostics and reagent metering files. The hardware component is a 56K-modem cable.

5. PC Console and Monitor
CX PRO Systems have an upgraded PC console with Pentium Microprocessor hard drive with CD-ROM and floppy disk drive, as well as a new flat panel LCD monitor.

6.0 Intended Use

The Beckman Coulter SYNCHRON CX Systems are fully automated and computer controlled instruments designed for the in vitro diagnostic quantitation of biological fluid components and therapeutic drugs as well as the qualitative determination of drugs of abuse in urine.

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The SYNCHRON CX Delta systems (CX4 Delta, CX5 Delta, CX7 Delta, CX9 ALX) have been upgraded to a CX PRO system through a software update and the following hardware upgrades: Obstruction Detection and Correction components, PC console and flat panel monitor, and Modem Connection components. There is also a name change to CX PRO.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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JUL 9 2001

Re: 510(k) Number: K011465
Trade/Device Name: Synchron CX® Pro Systems: Synchron CX4 Pro, Synchron CX5 Pro, Synchron CX7 Pro, Synchron CX9 Pro

Regulation Number: 862.3030, 862.1030, 862.1035, 862.1050, 862.1065, 862.3100, 862.1070, 866.3720, 862.1100, 862.3150, 862.3170, 862.1110, 862.1145, 862.3870, 862.3645, 862.1160, 862.1170, 862.1175, 862.3240, 862.1215, 862.1215, 862.3250, 862.1225, 866.5270, 862.3320, 862.3040, 862.3450, 862.1360, 862.1345, 864.7470, 862.1175, 866.5510, 866.5510, 866.5510, 862.1410, 862.1415, 862.1440,862.1440, 862.1460, 862.1465, 862.1495, 862.3620, 862.3630, 866.5040, 862.3650, 862.3660, 862.3350, 862.1580,862.1600, 866.5060, 862.3700, 862.1635, 866.5775, 862.3830, 862.1665, 862.3880, 862.1700, 862.3900, 866.5880, 862.1705, 862.1715, 862.1770, 862.1775, 862. 2160, 862.3645
Regulatory Class: I, reserved
Product Code: JIF, DIH, JIY JGJ, CEO, JHB
Regulatory Class: II
Product Code: LDP, CKA, CJW, CJE, DKZ, JFJ, GTQ, CIT, DIS, JXM, JFM,JFP, CIG, CJY, LDJ, KLT, JFL, CGZ, CHH, CGS, JHW, DIO, CGX, DCK, KXT, DMT, LCD, JQB, CGA, LCP, CHH, DEW, CZP, DFT, JMO, CFJ, CFR, JGG, CHI, DJR, KXS, DCF, DJG, LCM, DLZ, DIP, CEM, JZJ, JXN, CEK, DHR, DKJ, JGS, KLS, KLI, LCR, DDG, CDT, KHQ, CDQ, LEG, JJE, JFP, CFR
Dated: May 11, 2001
Received: May 14, 2000

Dear Ms. Tang:

This corrects the substantially equivalent letter dated June 8, 2001 regarding the omission of product codes (JJE, JFP, CFR) and regulation numbers (862.2160, 862.1145, 862.1345).

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the

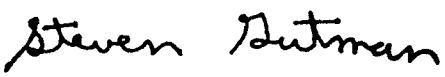
Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number (if known)

Device Name OTW VIATRAC™ 18 Peripheral Dilatation Catheter

Indications for Use

The OTW VIATRAC™ 18 Peripheral Dilatation Catheter is indicated:

- To dilate stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries)
- For the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- For post deployment optimization of the 28 mm and 38 mm MEGALINK™ Biliary Stent (6.0 to 10.0 mm diameters) and 18 mm MEGALINK™ Biliary Stent (6.0 to 8.0 mm diameters).

The OTW VIATRAC™ 18 Peripheral Dilatation Catheter is not intended for use in the coronary vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Indications for Use Statement

510(k) Number (if known)

Device Name

RX HERCULINK™ 14 Biliary Stent System
RX HERCULINK™ PLUS Biliary Stent System
RX & OTW MEGALINK™ SDS Biliary Stent Systems

Indications for Use

The RX HERCULINK™ 14, RX HERCULINK™ PLUS, and the RX & OTW MEGALINK™ SDS Biliary Stent Systems are indicated:

- For the palliation of malignant strictures in the biliary tree.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)